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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,700	09/18/2003	Robert H. Keller	930068-2005	4715
20999	7590	04/18/2005	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			MCCORMICK EWOLDT, SUSAN BETH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/664,700

Applicant(s)

KELLER, ROBERT H.

Examiner

Susan B. McCormick-Ewoldt

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) 22-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### **Election/Restriction**

Applicant's election with traverse of Group I in the reply filed on March 9, 2005 is acknowledged. The traversal is on the ground(s) that the claims are drawn on the same invention and the search for both groups would overlap. This is not found persuasive because Group I involves a composition and Group II is related to method of reducing weight in a patient.

Claims 22-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claims, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 9, 2005.

The requirement is still deemed proper and is therefore made FINAL.

#### **Claims Pending**

Claims 1-21 and 44-46 will be examined on the merits.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using *Viscus album* for raising endorphins and chromium ions, chromium niconalate and Tremella mushroom for increasing insulin sensitivity, does not reasonably provide enablement for any agents capable of raising endorphins or increasing insulin sensitivity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue

Art Unit: 1654

experimentation. The key word is “undue,” not “experimentation.” ” (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. “Whether undue experimentation is needed is not a single, simple factual considerations.” (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case, are discussed below.

The invention is targeted to a composition comprising *Viscus album* for raising endorphins and chromium ions, chromium niconalate and Tremella mushroom for increasing insulin sensitivity, bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments. Thus, claims to a composition may be unbelievable in the absence of strong supporting evidence. It is noted that the instant claims encompasses various conditions i.e. weight loss, raising endorphins, increasing insulin sensitivity and slowing digestion, for example, and yet the instant specification provides no guidance that would permit the skilled artisan to use the invention with any agent capable of raising endorphins and for increasing insulin sensitivity.

In the instant case, Applicant has disclosed that the claimed composition is useful in *Viscus album* for raising endorphins and chromium ions, chromium niconalate and Tremella mushroom for increasing insulin sensitivity. The claims specifically disclose *Viscus album* for raising endorphins and chromium ions, chromium niconalate and Tremella mushroom for increasing insulin sensitivity, while in the specification, Applicant provides no guidance that would permit the skilled artisan to practice the invention commensurate with the *scope* of the instant claims with regard for any agents capable of raising endorphins or increasing insulin sensitivity. Applicant shows an example of weight loss, as is claimed (see page 10-11).

Art Unit: 1654

Since there is a working example, one also must consider the guidance provided by the instant specification and the prior art of record. As stated *supra*, the state of the art is unpredictable as it reflects that there is no conclusive evidence that the composition will treat any agents capable of raising endorphins or increasing insulin sensitivity.

It is noted that there is not a single example in the instant specification, *working or prophetic*, which indicates that any agent of the instant disclosure would treat any agents capable of raising endorphins or increasing insulin sensitivity. For example, the data found in the specification is inconclusive to support the breadth of the claimed invention. Taking the examples of pages 10-11 into consideration, it appears that Applicant has found some effect in weight loss. However, again, there is no indication that this response can be reasonably extrapolated to any agents capable of raising endorphins or increasing insulin sensitivity.

Again, the claims are drawn to specifically a composition comprising *Viscus album* for raising endorphins and chromium ions, chromium niconalate and Tremella mushroom for increasing insulin sensitivity. However, Applicant has not reasonably correlated to the breadth of the claimed invention. The skilled artisan would not have a reasonable expectation that the response displayed in the instant specification would reasonably treat any agents capable of raising endorphins or increasing insulin sensitivity lacking substantial evidence in the specification as well as the prior art pertaining to the claimed invention.

The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the skilled artisan with specific treatment regimens that achieve a therapeutic benefit; however, the specification does not provide such guidance and fails to provide evidence in a composition comprising an agent capable of increasing insulin and an agent capable of raising endorphins. Without such guidance in the specification and the lack of correlative working examples, the claims would ***require an undue experimentation without a predictable degree of success on the part of the skilled artisan.***

*In re Fisher*, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), held that “inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; ***however, he***

Art Unit: 1654

*must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.” (emphasis added).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 4-6, 15-18, 44, the term “increasing” is vague and indefinite because it is not clear how much or how far is encompassed by this term.

In claims 1, 2, 11, 12, 44-45, the term “raising” is vague and indefinite because it is not clear how much or how far is encompassed by this term.

In the claims 7, 8, 11, 14, 45, the term “slowing” is vague and indefinite because it is not clear how much is encompassed by this term.

In claims 5, 18, 21, 46 the term “niconalate” appears to be a misspelling. Applicant could mean picolinate but this is unclear. Clarification is needed. For the purpose of examination “niconalate” will be assumed to be a misspelling of “picolinate.”

Claim 7 recites the limitation “an agent capable of slowing digestion” in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21, 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maurel *et al.* (US 6,129,924), Wasser *et al.* (US 6,383,799), Alviar *et al.* (US 6,413,545) and DeFelice (US 5,560,928).

Maurel *et al.* (US 6,129,924) teach using an extract of *Viscum album* (i.e. mistletoe), sunflower oil and safflower oil (i.e. linoleic acids) and chromium in a composition for the treatment of insulin dependent or non-insulin dependent diabetes (column 7, line 49; column 8, lines 10-13; column 10, lines 65-67 and column 11, lines 1-3). Maurel *et al.* does not specifically teach using an agent that raises endorphin levels or chromium niconalate in the composition.

Wasser *et al.* (US 6,383,799) teach using Tremella mushrooms in a composition to control hypoglycemia (column 1, lines 8-20 and column 4, lines 52-60).

Alviar *et al.* (US 6,413,545) teach a diet composition with the effective amounts of chromium picolinate to help control the appetite and conjugated linoleic acid that are used to reduce body fat (column 4, lines 8-12 and column 5, lines 23-39).

DeFelice (US 5,560,928) teaches the use of kelp for use in a dietary supplement and also the use of chromium (column 3, lines 27-30).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions for insulin activity and weight loss which are well known to be important in controlling diabetes. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Art Unit: 1654

Based on the disclosure by these references that these substances are used in compositions for insulin activity and weight loss, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references taken together teach the ingredients for a composition. The references show that is well known in the art to use the ingredients in insulin activity and weight loss. Thus a person of ordinary skill in the art would reasonably expect that the ingredients from the references could successfully be used in a composition for insulin activity and weight loss. Based on this reasonable expectation for success, a person of ordinary skill in the art would be motivated to modify the teachings of the references to include the ingredients from the references for insulin activity and weight loss.

From the teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

#### Summary

No claim is allowed.

#### Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

Art Unit: 1654

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Susan D. Coe*  
4-12-05  
**SUSAN COE**  
**PRIMARY EXAMINER**